K051304

JUN 8 2005

510(K) Summary

Submitter's Name:	iScience Surgical Corporation
Submitter's Address:	3696A Haven Avenue Redwood City, CA 94063
Submitter's Telephone:	Phone (650) 421-2700 Fax (650) 421-2701
Contact Name:	Ron Yamamoto
Date Summary was Prepared:	April 20, 2005
Trade or Proprietary Name:	iScience Surgical Ophthalmic Imaging System (OIS)
Common or Usual Name:	Ultrasound Echo Imaging System
Classification Name:	System, Imaging, Pulse Echo Ultrasound

Predicate Devices:

Device Name	510(k) Number
UBM Plus, Model P45	K003141
Artemis Ultrasonic Arc-Scan System	K021333

Description of the Device and Summary of the Technological Characteristics:

The Ophthalmic Imaging System (OIS) is an ultrasound system designed for noninvasive imaging of the anterior segment of the eye through the use of standard ultrasound imaging pulse-echo techniques.

The system consists of a handpiece containing a high-frequency transducer, connected to interfacing electronics in the Transducer Interface Module (TIM) which is in turn connected to a personal computer with video display. Software developed by iScience Surgical runs on the computer controlling the system and generating the image.

The OIS is used with a sterile disposable tissue interface (Imaging Gel Cap) which is attached to the handpiece for direct contact with the eye during imaging. The OIS may also be used with a sterile Sheath Adapter Assembly for sterile field applications.

Substantial Equivalence:

The OIS device is similar to predicate devices such as the UBM Plus, Model P45 from Paradigm Medical Industries and the Artemis VHF Ultrasound Arc-scan System from Ultralink LLC. Like the OIS device, these predicate devices are intended to provide high resolution ultrasound images of the anterior portion of the eye. All systems use a very high frequency, mechanically scanned transducer and use patient contact materials that are biocompatible and have a history of use in medical devices. The images are all displayed on video and/or PC monitors. All systems have similar medical electronic controllers and utilize standard computer hard drives to store images.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 2005

iScience Surgical Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K051304
Trade Name: iScience Surgical Ophthalmic Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYO and ITX
Dated: May 16, 2005
Received: May 19, 2005

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the iScience Surgical Ophthalmic Imaging System, as described in your premarket notification:

Transducer Model Number

OIS-HP-80A

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all

the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Dr. Ewa Czerska at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

K051304

4.3 Indications for Use

System: iScience Surgical Ophthalmic Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PW D	CW D	Color Dopp	Comb. Modes	Other
Ophthalmic	Ophthalmic	N						
Fetal Imaging & Other	Fetal							
	Abdominal:							
	Intra-operative (Spec.)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatricd:							
	Small Organ (Thyroid, Breast, Testes, etc.):							
	Neonatal Cephalic:							
	Adult Cephalic:							
	Trans-rectal:							
	Trans-vagina							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.):							
	Musculo-skel. (Superfic):							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel:							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The OIS provides real-time, high-resolution images of the intraocular anatomy and is, therefore, useful in evaluation of pathologies of the anterior segment such as trauma, tumors, cysts, and glaucoma. It can also be used during ophthalmic surgery to monitor the changes in anatomical structures such as the anterior angle, Schlemm's canal and related outflow structures of the eye, for glaucoma management.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051304

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